DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-450/S-007

Parke-Davis Pharmaceutical Research
c/o Pfizer, Inc as Agent
Attention: Andrea Garrity
Director, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017

Dear Ms. Garrity:

Please refer to your supplemental new drug application dated November 13, 2001, received November 14, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cerebyx® (fosphenytoin sodium injection).

This "Changes Being Effected" supplemental new drug application provides for revision of the labeling to reflect the addition of the Pfizer Inc. name.

We have completed the review of this supplemental application and it is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Jacqueline H. Ware, Pharm.D., Regulatory Management Officer, at (301) 594-5533.

Sincerely,

{See appended electronic signature page}

Maryla Guzewska, Ph.D.
Chemistry Team Leader, Neurology Drugs for the
Division of Neuropharmacological Drug Products,
(HFD-120)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Maryla Guzewska
1/2/02 08:37:01 AM